

ENZYMATIC THERADY

NF Formulas • PhytoPharmica Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 * F: 503.582.0467 +

INTEGRATIVE THERAPEUTICS INC."

PHYTOPHARMICA

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 • F: 920.469.4418 (Phyto)

DC?

'NEDEBORATED What Better feels like"

October 19, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

HEROMBON IN		
Similase®	Similase® is the most potent plant based enzyme product available.* Similase is a combination of plant enzymes to support complete digestion of all types of nutrients, such as carbohydrates, proteins, and fats.* The blend of enzymes is unique because it is active across a broad pH range in the digestive tract.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 10/19/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Chief Financial Officer

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October 20, 2004

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Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

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Similase®	A comprehensive, high-potency Plant Enzyme supplement that supports digestion of all food groups.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

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By: KIRCHE

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 10/20/04

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A PRODUCKER.		
Similase®	Unlike animal-derived pancreatic enyzmes, Plant Enzymes in Similase are acid-stable and active from pH 2 to12. As a result, Similase supports digestion of proteins, carbohydrates, fats, fiber and phytates under virtually all gastrointestinal pH conditions.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

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Michael P. Devereux Chief Financial Officer